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alfresa

FIT AA01 Specimen Diluent

Product list

Catalogue No.	Product name
913937	FIT AA01 Specimen Diluent

Manufactured by:

Alfresa Pharma Corporation
2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan
For any incidents: incident-ivdr@alfresa-pharma.co.jp
For technical support: technical-support@alfresa-pharma.co.jp

European Authorized Representative

Emergo Europe
Prinsessegracht 20 2514 AP The Hague The Netherlands

Refer to the following URL for the package inserts in languages other than English:
https://alfresa-pharma-global.com/fit/products/

CE

FOR *IN VITRO* DIAGNOSTIC USE ONLY

1.0 INTENDED USE

FIT AA01 Specimen Diluent is a diluent for high concentration specimen. High concentration specimen over the assay range has to be diluted with this diluent and be retested.

2.0 COMPONENTS

A pack includes two bottles of 8 mL **FIT AA01 Specimen Diluent**.
FIT AA01 Specimen Diluent contains:

MES Buffer	30 mmol/L
Sodium chloride	1.1 %
Bovine serum albumin	0.15 %
Boric acid	0.4 %
Sodium azide	< 0.1 %

FIT AA01 Specimen Diluent contains 0.4 % boric acid and less than 0.1 % sodium azide.
For safety precautions, see **6.0 WARNINGS AND PRECAUTIONS**. Safety Data Sheet is available upon request by users.
Hazard statements:

- May damage fertility
- May damage unborn child

3.0 ADDITIONAL REQUIRED EQUIPMENT

3.1 Analyzer

Discrete Clinical Chemistry Analyzer AA01

3.2 Specimen Collection Container

Specimen Collection Container A

4.0 REAGENT PREPARATION

FIT AA01 Specimen Diluent is supplied ready to use.
Set **FIT AA01 Specimen Diluent** on the reagent table of **Discrete Clinical Chemistry Analyzer AA01**. When high concentration specimen is measured, it is automatically diluted with **FIT AA01 Specimen Diluent** by **Discrete Clinical Chemistry Analyzer AA01**.

5.0 STORAGE AND SHELF LIFE AFTER FIRST OPENING

5.1 Storage

Store at 2–8 ℃. Use **FIT AA01 Specimen Diluent** within expiry date on the box and bottle label.

5.2 Storage and shelf life after first opening

Tightly keep the lid on and store at 2–8 ℃ after opening **FIT AA01 Specimen Diluent**. Use it within one month.

6.0 WARNINGS AND PRECAUTIONS

6.1 General precautions

For *in vitro* diagnostic use.
Only experienced laboratory personnel should use this; the test should be used in a manner consistent with Good Laboratory Practice. If you become aware of a serious incident related to this product, be sure to report it to the manufacturer and the competent authorities.

6.2 Safety precautions

1. Do not pipet by mouth.
2. **FIT AA01 Specimen Diluent** contains 0.4 % boric acid. Reproductive toxicity: May damage fertility or the unborn child. Obtain special instructions before use. If exposed or concerned: Get medical advice/attention.
3. **FIT AA01 Specimen Diluent** contains less than 0.1 % sodium azide. Upon exposure to the eye or skin or accidental ingestion, take emergency measures such as washing with plenty of water. Consult a doctor if necessary.
4. Do not smoke, eat, or apply cosmetics in areas where patients' specimens or kit reagents are handled.
5. Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
6. Take care to avoid self-inoculation, splashing to the mucous membrane, or generation of aerosols.
7. Wear laboratory gloves while handling patients' specimens or disposing of solid or liquid wastes.
8. Cautions upon disposal
   1) **FIT AA01 Specimen Diluent** contains less than 0.1 % sodium azide. Sodium azide can react with copper and lead plumbing to form explosive metal azides. Regulations currently in use regarding dangerous waste elimination must be followed. If disposed in the sink, rinse with plenty of water.
   2) Upon disposal of reagents or other materials, comply with relevant legal provisions.
   3) **FIT AA01 Specimen Diluent** contains 0.4 % boric acid. Upon disposal comply with relevant legal provisions.
9. **FIT AA01 Specimen Diluent** contains bovine serum albumin free from known infectious agents. However they should be considered potentially infectious and handled with care to avoid infection.
10. All human specimens should be considered potentially infectious. Handle all specimens as if capable of transmitting HBV, HCV, HIV, or other microbes. Decontaminate and dispose of specimens and all potentially contaminated materials as if they contain infectious agents.

6.3 Limitations

1. Do not use reagent bottles for purposes other than those stated.
2. Do not damage or stain the bar codes on the labels of each bottle.
3. Do not replenish or mix reagents. Also, do not mix reagents of different bottles even if they have the same lot number.
4. Use of reagents, disposables, or spare parts other than those supplied by the authorized distributor may produce incorrect results.
5. Do not recycle the bottle. It may be infectious.

7.0 CALCULATION OF EXAMINATION RESULTS

Concentration of the undiluted high concentration specimen is automatically calculated by **Discrete Clinical Chemistry Analyzer AA01** according to the dilution factor.

8.0 PERFORMANCE CHARACTERISTICS

Claimed repeatability: CV ≤ 15 %
According to the in-house data, when the high concentration specimen of fecal calprotectin was automatically diluted with **FIT AA01 Specimen Diluent** by **Discrete Clinical Chemistry Analyzer AA01** and the measurement was repeated 5 times under the same conditions, the coefficient of variation (CV) of the measured values were 1.1–3.5 % at 10–fold dilution and 1.0–1.3 % at 100–fold dilution.

9.0 LIMITATION OF THE EXAMINATION PROCEDURE

1. Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing, because blood contamination may influence measurements.
2. Appearance changes, such as cloudiness and aggregation, in any of the reagents indicate the possibility of deterioration. Call your local dealer for advice.
3. As with all assays, the results of this test, can be influenced by factors present in some patients' specimens.
4. For diagnostic purposes, the results obtained from this assay should always be used in combination with a clinical examination, patient medical history, and other findings.
5. Procedural directions must be followed exactly because any modification of the procedure may change the results.
6. Use of reagents, disposables, or spare parts other than those supplied by the authorized distributor may produce incorrect results.
7. Store the reagents according to the storage methods. Do not use them after the expiry date.

10.0 SYMBOLS USED IN PRODUCT INSERTS AND ON LABELS

Symbols	Meanings of the symbols
CE	CE marking
	Use-by date (Expiry date)
LOT	Batch code
REF	Catalogue number
	Manufacturer
EC REP	Authorized representative in the European Community (Authorized European representative)
IVD	*In vitro* diagnostic medical device (*In vitro* diagnostic)
	Temperature limit (for storage)
	Consult instructions for use
	Caution: Products containing hazardous substance
Diluent	Specimen diluent
	May damage fertility May damage unborn child